Sample QA Plan

LABORATORY NAME
CLIA #
LAB DIRECTOR

Quality Assurance Plan

The (Lab Name) provides service to (_____). The primary mission is to provide (DESCRIBE WHAT TYPE OF TESTING).

This quality assurance (QA) program monitors and evaluates the quality of the services provided. The laboratory director or designee oversees the implementation of the QA plan and helps identify and correct problems as they occur. The QA plan is periodically reviewed to minimize the possibility of recurrence of problems. Areas for improvement to the QA plan will be implemented where applicable.

The QA program is designed to:

- Evaluate the effectiveness of the laboratory's policies and procedures
- Identify and correct problem
- Ensure accurate, reliable, and prompt reporting of test results
- Ensure the adequacy and competency of the laboratory staff
- Meet all regulatory requirements as they apply to the services offered

Techniques are constantly being refined, tested against controls, and documented so that other scientists and testing personnel with the appropriate background can duplicate the results. Quality Assurance is maintained through detailed and thorough discussion of techniques. Results and problems are shared regularly in laboratory meetings, individual meetings, and on a wider scale through peer reviewed publications in scientific journals. Problems identified through these processes and corrective actions are documented. The documentation of problems and corrective actions is reviewed to assess whether the action taken has prevented recurrences.

Test results that appear inconsistent with patient history, symptoms, diagnosis, or pertinent clinical data are evaluated for clerical and technical error. The same specimen and/or an additional specimen of the same type may be obtained for retesting when possible. In addition, if no clerical errors are identified, there will be a review of the patient test management process, the testing system, and the reporting system. Findings will be documented and if necessary, revisions will be made in test criteria for patient preparation, collection, labeling, preservation, transportation or specimen rejection.

Each investigator, physician and testing personnel is encouraged to communicate problems or concerns in a timely manner. All complaints will be investigated and the resolution of the complaint will be documented. All quality assurance records include the

problems identified, corrective action taken and are maintained for a minimum of two years.

Quality Control

All tests are validated before reporting patient results. Written policies are available which describe the procedures for quality control for each test performed. The controls are tested in the same manner as patient samples and the results are recorded. Control data is reviewed and documented as acceptable or unacceptable. If the control values are unacceptable, an investigation is done and documented. No patient results are reported until the controls are within acceptable ranges. Any problems detected during evaluation of control data or errors in reported results are documented, investigated and the action taken is recorded. Quality control records are kept for at least two years.

Describe your Quality Control measures for each individual test
Include type and source of control

Test 1-PCR
For example:
Each time a test is run, both a positive and negative control are run at the same time and the test is repeated to reproducibility and /or both strands of DNA are sequenced and /or a restriction site is tested
Use of water control to detect contamination
Pipettemen, anti-aerosol cotton packed pipette tips, water, buffer, and reagents are dedicated to clinical PCR testing
Gloves are worn Use of virgin disposable plastic ware for all pipettes and tubes, without reuse.

Test 2-ELISA
Standard curve is run
Each test is run in duplicate for reproducibility

Use of virgin disposable plastic ware for all pipettes and tubes, without reuse

Reagent Tracking

Reagents are monitored for labeling, lot number, and expiration date to ensure quality testing.

Reagents are dated when received and again when opened. Reagents that do not have an expiration date are assumed to be expired [one year] from the date opened. Reagents, solutions, control materials, calibration materials, and other dated supplies will not be used when they have exceeded the expiration date, deteriorated, or are of substandard quality.

Describe your method for reagent tracking

For example:
-Reagent log
Reagents are recorded on the reagent log along with the expiration date, lot number, and receipt date. Open dates and staff initials are recorded when the reagents are put in use.
-Lab notebook
Reagent lot numbers and expiration dates are recorded for each run

Remedial action

The testing personnel will correct and document problems in controls, equipment, and or reagents as they occur. The results and date of the remedial action will be entered [in the laboratory notebook or a QA log]. Any remedial action taken by the laboratory will be documented on the [corrective action form] and reviewed by the laboratory director.

PROCEDURE MANUALS

The procedure manual or laboratory notebook contains the procedures for all techniques used in this laboratory. All testing procedures are available as written documents and include any modifications to the methods. The procedure manual is reviewed annually by the laboratory director or designee. Approval of laboratory procedures is indicated by the date and signature of the laboratory director on the cover sheet of the procedures or the procedure manual.

EQUIPMENT MONITORING

Prior to delivery, instruments are calibrated by the manufacturer. The laboratory follows manufacturer's instructions for the operation and maintenance of all instruments used in the test procedures. Equipment that requires calibration will be calibrated according to the manufacturer's instructions. Problems or concerns are addressed by a service call or repeat of maintenance or calibration. Centrifuges, pipettes and non-NIST traceable thermometers are calibrated every 6 months. All equipment records are kept for a least two years.

Equipment monitoring

- Temperature checks
[Temperature may be monitored manually, or by electronic monitoring or by building engineers. Please indicate how your equipment will be monitored.]
For example:

1. Refrigerator 1-daily manual recording on temp log
2. Refrigerator 2- on electronic alarm
3. -20C freezer- REES system
4. Incubator-daily manual recording on temp log

- Routine maintenance
Check operators manual for required daily, weekly, monthly and /or yearly maintenance List here.

1. Perkin Elmer 9600 PCR unit 2.
2. ABI 310 sequencer 3.
3. HPLC 4.
4. Spectrophotometer
5. -

- 6 month calibrations

1. centrifuge
2. pipetteman

- Other equipment

1. -

Indicate where instrument records are kept

If the laboratory utilizes two instruments interchangeably for the same test, studies must be performed to validate that the results are comparable. Twice a year, the same test will be performed using different instruments to evaluate the accuracy and reliability of the results. Criteria for acceptable variation of instruments have been established.

Instruments such as freezers, refrigerators, and incubators that contain samples or reagents are monitored manually or electronically by alarm system and recorded during regular laboratory hours. Instruments that are used intermittently, such as waterbaths or incubators must be monitored on the day of use. The acceptable temperature range is indicated on the temperature log. Ambient room temperature between 50and 90 F is appropriate for testing procedures. NIH maintenance personnel correct any severe changes in room temperature. Thermometers used are calibrated against a National Institute of Standards and Technology (nist) thermometer or are NIST traceable

Patient Test Management

Testing is requested by referring physicians or through NIH patient recruitment. Written instructions are provided to the physician or patient for obtaining quality specimen including policies for specimen container, volume, and transportation criteria. All samples are labeled with a name or a unique identifier.

Test Requisition

Test requisition includes:

1. Name of patient with identifier
2. Name and address of individual ordering test
3. Test to be performed
4. Date of collection
5. Any other pertinent information

A test requisition must accompany the specimen and include a unique identifier, name and address of ordering physician or investigator, test(s) requested, and any other pertinent information. Oral requests must be documented in writing. Requisitions are kept for 2 years.

Describe your requisition here

Specimen labeling

Include **your** lab's specific requirements for the labeling at time of collection

For example:

1. Patient name
2. Chart number
3. Date of collection

Specimen accessioning A specimen accession log is used to record specimens received for testing.

Describe where/how specimens are accessioned in your laboratory
For example:
A number is assigned to the sample by the laboratory. Patient name and or ID from sample tube is recorded on specimen log. Date rec'd , storage location if applicable, initial of person receiving sample are documented.

Rejection criteria

Specimens are rejected if they are unlabeled or improperly labeled or preserved. If incomplete information is submitted, attempts made to receive the necessary information are documented in specimen log. If the specimen is unacceptable or inadequate for testing, a repeat specimen is requested when possible. If the test is performed and results are reported on a less than optimal specimen, the condition of the specimen is also recorded on the test report for proper interpretation by the patient care provider. Problems involved with obtaining an appropriate specimen and corrective action taken are documented. Corrective actions taken to minimize communication breakdowns are evaluated for effectiveness.
[If you have other specific criteria include them in this text]

Test Turn around time

Include here your test turnaround time

For example:
Tests are performed in batches every 3 to 4 weeks but the nature of genetic testing is that it may take many months to complete the analysis.

Laboratory Test Records

Laboratory raw data must include the following information:

1. Date test performed
2. Patient name or unique identification
3. Test name
4. Test result
5. Initial or name of individual performing the test
6. Documentation of quality control-acceptable or unacceptable
7. Unit of measure, and normal ranges (if applicable)

Indicate where lab data is recorded, i.e. individual laboratory notebook, experiment logs, data flow sheets, etc.

Test Report

The laboratory director signs all reports after reviewing the test procedures and the results. The report includes the referring physician's name, address and phone number, a description of results, an interpretation of these results, recommendations to the referring physician, as well as the Director's signature, title and address and the date of the report. Copies of reports are kept on file for a minimum of two years. Test results are confidential and are kept [in locked files; password-protected database or rooms that are locked when unoccupied]. Results are released only to authorized individuals.

Proficiency Tests and Competency Checks

Proficiency
Twice a year, a blinded previously tested specimen is repeated to ensure the accuracy of the test result. Acceptable and unacceptable limits for agreement of quantitative results must be determined. The expected results of this blind specimen will be recorded as well as the actual results, the name of the testing personnel, the date the test was performed and the signature of the lab director or designee to document personnel competency requirements. Corrective action taken for unacceptable proficiency results or personnel competency checks must be evaluated for effectiveness.

Describe how proficiency testing will be performed include the type and source of the proficiency sample and the limits for acceptability. Define the limits of acceptability to your specific testing program.

Example:
Acceptable limits for agreement of results are generally + 30% for the values recorded for the previous result. For samples where concentrations of analytes are below 50 pg/mL, the acceptable limits of from +15% the median value are relaxed according to the guidelines detailed below:

Range	Acceptable limits
10 pg/mL	± 100%
11-30 pg/mL	± 50%
31-50 pg/mL	± 30%
>50 pg/mL	± 15%

Competency
New testing personnel must show initial competency prior to reporting results and again at six months. Once per year, all testing personnel will have their competency documented by performing the proficiency testing. Personnel who do not successfully complete the competency checks must receive additional training and perform an additional competency check prior to signing out patient test results.

Competency/Proficiency records

List how and where competency /proficiency testing records will be recorded

Example:
The results will be recorded on Competency/proficiency forms in the CLIA Compliance Notebook

Personnel Qualifications

Documentation of the educational background and experience of all testing personnel is required. Each laboratory is responsible for having on file Curriculum Vitae for the director, and photocopy of the highest degree earned. Other individuals involved in laboratory testing are required to have a photocopy of the highest degree earned on file.

Safety

The NIH reviews and is responsible for all aspects of laboratory safety through the NIH Office of research Services.

> Radiation Safety - Radiation Safety Branch, Division of Safety, Office of Research Services 496-5774.
>
> OSHA - Occupational Safety and Health Branch, Division of Safety< Office of Research Services 496-2346.

Copies of Safety training sessions should be kept on file for all testing personnel.